CHPA

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October 11, 2007

The Honorable Henry A. Waxman
Chairman, Committee on Oversight and Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Dear Chairman Waxman,

Thank you for your letter of October 3, 2007, regarding the marketing of over-the-counter (OTC) cough and cold medicines for children. The member companies of the Consumer Healthcare Products Association (CHPA) consider consumer safety their top priority. Therefore, the leading manufacturers of children's cough and cold medicines are voluntarily withdrawing from the market products specifically intended for infants, including those whose packaging displays pictures of infants. This withdrawal does not affect products for children ages 2 and older.

This action is consistent with our industry's recent recommendation to the U.S. Food and Drug Administration (FDA) that all cough and cold medicines be labeled "Do Not Use" for children under two, and our members will be revising labeling on all products to reflect this statement. While all of the evidence supports the safety of OTC cough and cold medicines at recommended doses, reviews conducted this year by both FDA and CHPA indicate that serious outcomes, including deaths, have resulted from misuse leading to overdoses in infants.

The challenge before us is to reduce the misuse of safe medicines. Although labels have always directed parents and caregivers to ask a doctor before using cough and cold medicines for children under two, we believe a simple "Do Not Use" statement is needed to help prevent overdose and misuse. We are committed to a comprehensive, multi-year educational initiative to educate health care providers, parents, and caregivers about the overdose risks associated with the use of OTC medicines in children and to give them information on how to properly use these products.

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As you know, FDA is convening an advisory committee meeting on October 18th and 19th to examine a range of questions related to the safety and efficacy of pediatric OTC cough and cold medicines. We will be presenting more detailed information on our educational initiative at this meeting. You can be assured, however, that we will be reaching a wide audience through a variety of channels and with a number of partner organizations. We expect to begin this initiative immediately, pending input from the advisory committee and FDA.

Among the topics on the committee's agenda is a review of the evidence supporting FDA's current determination that these medicines are effective. Based on all of the evidence available at the time, FDA conducted a thorough review of these medicines in the 1970's, and finalized the applicable monograph in the early 1990s. Because recent advances in pediatric research have given us better tools to confirm the doses for these medicines in children under 12, we have presented to the committee our recommendations and commitments to conduct this additional research.

We appreciate your interest in our products, and share your commitment to ensuring consumer safety. We are available any time to discuss these issues further with you and your staff.

Yours truly,

Linda A. Suydam

Linda A. Suydam
President

Enclosure

cc: The Honorable Tom Davis
Ranking Minority Member